AANS/CNS SECTION ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES

American Association of Neurological Surgeons

A Section of the
American Association of Neurological Surgeons
and
Congress of Neurological Surgeons

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Subject: Health Technology Clinical Committee Findings and Coverage Decision on Vertebroplasty, Kyphoplasty & Sacroplasty

Ms. Santoyo,

The American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves would like to thank the you and Washington State Health Care Authority for the opportunity to provide comment on the Washington State Health Care Authority Health Technology Clinical Committee Findings and Coverage Decision on Vertebroplasty, Kyphoplasty & Sacroplasty from December 10, 2010. While we applaud the goal of improving patient care through application of scientifically grounded therapies, we have concerns regarding the over generalized conclusion that Vertebroplasty, Kyphoplasty and Sacroplasty procedures are not a covered benefit.

Coverage decisions frequently determine access to appropriate medical care, and based on your coverage decision, a patient with a pathological spinal fracture and kyphosis from multiple myeloma would be deprived the less invasive option of kyphoplasty and radiation, and possibly undergo a larger surgical procedure or accept unneeded disability. In a systematic review of the available literature regarding the use of vertebroplasty and kyphoplasty in patients with painful compression fractures associated with metastatic spine disease, there is a strong recommendation for vertebral augmentation as safe and effective in providing pain relief and improving functional outcome in patients with vertebral body fractures (Mendel 2009). The authors performed a review of the English literature with the results reviewed and discussed through consensus among a multidisciplinary panel of expert members of the Spine Oncology Study Group, commonly known as a Delphi technique, and with recommendations made according to the Guyatt Guidelines. They identified a total of 1665 abstracts, with 28 articles using vertebroplasty reported on 877 patients and 1599 treated levels, and 12 articles using kyphoplasty reported on 333 patients and 481 treated levels. They noted low complication rate, from 0% to 0.5%, and without

any neurologic complications. The most important finding was that pain and functional outcomes were universally successful using either technique. Based on this, they noted a strong recommendation for vertebral augmentation as safe and effective in providing pain relief and improving functional outcome in patients with vertebral body fractures and axial pain due to metastatic disease.

1. E Mendel, E Bourekas, P Gerszten, JD Golan. Percutaneous Techniques in the Treatment of Spine Tumors: What Are the Diagnostic and Therapeutic Indications and Outcomes?. Spine Volume 34, Number 22S, pp S93–S100.

We believe the conclusions drawn regarding the use of vertebral augmentation in vertebral insufficiency fractures are over broad in combining the select patients with acute compression fractures who benefit from vertebral augmentation, with those patients beyond 10-12 weeks who do not benefit from such procedures. In patients with acute fractures, less than 3 months, with well-defined pathology, both vertebroplasty and kyphoplasty are appropriate and beneficial medical options for patients. Published articles between 1980 and 2008 reporting outcomes after vertebral augmentation for osteoporotic fractures have generally supported these procedures (McGirt 2009). There were 74 studies for use of vertebroplasty in osteoporotic compression fractures, with 1 Level I, 3 Level II, and 70 Level IV studies; in addition to 35 studies for use of kyphoplasty with 2 Level II and 33 Level IV studies. Analysis noted superior pain control within the first 2 weeks of intervention compared with optimal medical management for osteoporotic vertebral compression fractures, with fair evidence (Level II–III) that vertebral augmentation results in less analgesia use, less disability, and greater improvement in general health when compared with optimal medical management within the first 3 months after intervention. Note that by 2 years after intervention, vertebral augmentation provides a similar degree of pain control and physical function as optimal medical management. However, much like a cavity filling, vertebral augmentation is meant for the treatment of the acute fracture and not for the long term treatment of osteoporosis at 2 years.

1. MJ McGirt, SL Parker, JP Wolinsky, et. Al. Vertebroplasty and kyphoplasty for the treatment of vertebral compression fractures: an evidenced-based review of the literature. The Spine Journal 9 (2009) 501–508.

There has been much talk regarding the studies by Buchbinder and Kallmes which included sham procedures. These two studies, which form the basis of your coverage decision, were downgraded by our AANS/CNS Joint Guidelines Committee (JGC) on the basis of flaws in the study, which have been acknowledged by the authors of the American Academy of Orthopedic Surgery (AAOS) guidelines, including the fact that they were both underpowered and that the external validity (generalizability) of these studies is questionable. Therefore, the “applicability” which is the process for determining the strength of recommendation is severely affected. These two studies have also been prominent in the AAOS guidelines on vertebral augmentation. In addition to the disagreement on the grading and interpretation of the studies by Buchbinder and Kallmes, our JGC expressed concern that two studies (FREE and Grafe) were unjustifiably downgraded to a level II, and inconsistent with the AAOS methodology used to craft their first recommendation. Due to these and other issues regarding the process and interpretation of the available articles, the AANS and CNS chose not to endorse the AAOS document.

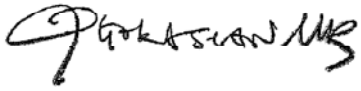
In summary, we believe that vertebral augmentation procedures are appropriate and beneficial in appropriately selected patients. The current coverage decision made by Washington State Health Care Authority is therefore over broad in combining the patients who benefit from

vertebral augmentation with those who do not. As coverage decisions frequently determine access to appropriate medical care, subsets of patients will be deprived access to appropriate and beneficial medical care.

Again, thank you for this opportunity to comment and we look forward to seeing the Health Technology Clinical Committee reconsider their Coverage Decision on Vertebroplasty, Kyphoplasty & Sacroplasty during their meeting on March 18, 2011.

If you have any questions, please feel free to contact Joseph Cheng, MD, AANS/CNS Coding and Reimbursement Committee at joseph.cheng@vanderbilt.edu or Cathy Hill, Senior Manager, Regulatory Affair AANS/CNS at chill@neurosurgery.org.

Sincerely,



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SPINE Volume 34, Number 22S, pp S93–S100

Percutaneous Techniques in the Treatment of Spine Tumors

What Are the Diagnostic and Therapeutic Indications and Outcomes?

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Study Design. Systematic review of the literature.

Objective. Should cement augmentation procedures such as vertebroplasty and kyphoplasty be used in patients with painful compression fractures associated with metastatic spine disease? What is the role of embolization in the treatment of metastatic spine disease?

Summary of Background Data. Vertebral augmentation is commonly employed in treating osteoporotic fractures and is now increasingly used in the management of pain in patients with spinal tumors. Intra-arterial and transcutaneous embolization techniques are also available in the management of spinal tumors. To date, the effectiveness and safety of these procedures have not been adequately demonstrated.

Methods. A review of the English literature was performed in Pub-Med. One search was performed using the following keywords: cancer, tumor, vertebroplasty, kyphoplasty, vertebral augmentation, outcome, safety, pain, and quality of life. A Second search was performed using the keywords: embolization, spinal, and tumors. Original studies reporting on at least 10 patients were included and systematically reviewed. The results were reviewed and discussed through consensus among a multidisciplinary panel of expert members of the Spine Oncology Study Group. Recommendations were made according to the Guyatt Guidelines.

Results. A total of 1665 abstracts were identified. Twenty-eight articles using vertebroplasty reported on 877 patients and 1599 treated levels. Medical and neurologic complications varied from 0% to 7.1% and 0% to 8.1%, respectively. Twelve articles using kyphoplasty reported on 333 patients and 481 treated levels. Medical complication rates varied from 0% to 0.5%, without any neurologic complications. Pain and functional outcomes were universally successful using either technique. Ten studies on embolization reported on 330 patients. There were 4 permanent complications (1.4%). Complete or partial embolization was possible in 97.5% with an estimated reduction of intraoperative blood loss of 2.3 L.

Conclusion. There is strong recommendation and moderate evidence for vertebral augmentation as safe and effective in providing pain relief and improving functional outcome in patients with vertebral body fractures and axial pain due to metastatic disease. There is a strong recommendation and very low evidence for embolization techniques as safe and effective in decreasing intraoperative blood loss in hypervascular tumors.

Key words: vertebral augmentation, vertebroplasty, kyphoplasty, embolization, spine cancer, spinal tumors. **Spine 2009;34:S93–S100**

The advent of percutaneous procedures has greatly expanded treatment options in the management of primary and secondary spine tumors. Their limited invasiveness makes them attractive to a variety of clinicians and patients alike.

Vertebroplasty and kyphoplasty are among the most commonly used treatments in spinal oncology for axial mechanical pain. Vertebroplasty is a percutaneous technique where radiopaque polymethylmethacrylate cement is injected under fluoroscopic control, while kyphoplasty involves initial inflation of a balloon within the vertebral body before injection of polymethylmethacrylate. The cement reinforces and stabilizes fractures.[1] It may also have antitumor activity as a result of cytotoxicity,[2] and thermal effect.[3] In addition, vertebral biopsies can be readily performed during these procedures if the etiology of vertebral abnormality is unclear or to confirm a suspected pathology.

Embolization is another frequently performed technique in the treatment of spinal tumors. It is usually intra-arterial but may also be done directly via transcutaneous routes. The main indication before surgery is to reduce blood loss during resection of vascular tumors. Additionally, embolization may be used in a palliative fashion for pain and local oncological control of tumors in patients that are not operative candidates.

A growing international experience with these percutaneous procedures is clarifying their usefulness and indications. The goal of this study was to systematically review the published literature on the safety and effectiveness of vertebroplasty, kyphoplasty, and embolization in the treatment of spinal tumors and then make treatment recommendations based on the best available literature and consensus expert opinion.

Methods

Vertebral Augmentation

A systematic review of the English literature was performed to answer 2 research questions that were determined through con-

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sensus following discussion among a multidisciplinary panel of experts (Spine Oncology Group). Question 1: Should cement augmentation be used in patients with painful compression fractures associated with metastatic spine disease? Question 2: Should embolization procedures be used in hypervascular metastatic tumors?

The first search was performed using PubMed with the following keywords: (1) cancer or tumor; (2) vertebroplasty, kyphoplasty, or vertebral augmentation; and (3) outcome, safety, pain, or quality of life. All abstracts were reviewed between September 3, 2008 and September 30, 2008. Original peer-reviewed articles including at least 10 patients with primary or secondary spinal tumors were included. Review articles, biomechanical, and basic science studies were excluded. Studies combining vertebral augmentation with other treatment methods such as radiofrequency ablation, radiosurgery, radiation therapy, and alcohol ablation were included. Articles including osteoporotic fractures or cementoplasty of bones other than vertebrae were only included if relevant primary clinical data were reported separately and specifically on at least 10 patients with spinal tumors. The references of these articles were reviewed to identify additional studies. The second search was performed using PubMed with the following keywords: (1) embolization; (2) spinal; and (3) tumors. The search was performed on December 15, 2008. Review articles were excluded. Only studies that included at least 10 patients were reviewed. Selected articles were graded according to the US Preventive Services Task Force hierarchy of research design.[4]

Studies were reviewed using a standardized data collection form. The type of study (prospective or retrospective) was noted. Data were collected on technique (vertebroplasty or kyphoplasty, fluoroscopy or computed tomography-assisted, type of cement used, levels treated, uni- or bilateral injection), treatment indications and exclusions, the total number of patients and levels treated, the total number of patients treated with tumors and the number of levels treated, and the type of tumors treated. The methods of clinical and radiologic pre- and postoperative evaluations were recorded. All temporary and permanent complications were collected, including locations and consequences of cement extravasations, as well as adjacent segment fractures and new levels requiring treatment. Some authors were contacted directly to clarify certain aspects of their studies.

A meta-analysis using the prospective studies was not possible due to the heterogeneity of study designs, inconsistent reporting of complications, and the use of different grading scales for pain and functional outcomes. Some studies reported results of their statistical analyzes by grouping osteoporotic and tumor patients, whereas others did not perform statistical analysis on pain and functional outcomes. Whenever possible, primary data were collected to calculate the mean preoperative, mean postoperative, and mean improvement in pain and functional outcomes as determined by the various scales and questionnaires used in each study. Changes in preoperative and postoperative scores were analyzed using one-sided paired Student *t* test. Standard deviation and the 95% confidence intervals were also calculated with an alpha value of 0.05. All statistical analyzes were performed using Microsoft Excel.

The results of the literature reviews, evidentiary tables, and preliminary conclusions were used to answer 2 research questions. A summary of the best available literature and answers to the questions were presented to the SOSG. A consensus-based decision-making process using a modified Delphi approach was then taken by the SOSG to make final treatment recommendations. The recommendations were either strong or weak as per the GRADE recommendation methodology.[5]

■ Results

Vertebral Augmentation

A total of 1396 abstracts were identified using the various keywords. Many of these articles were identified on multiple searches. All abstracts were reviewed and the complete texts of all potential articles were retrieved. Six prospective[6–11] (level II) and 22 retrospective articles[12–33] (level III) using vertebroplasty reported on a total of 877 patients and 1599 treated levels (Table 1). Seven prospective[34–40] (level II) and 5 retrospective articles[14,23,25,30,41] (level III) using kyphoplasty reported on 333 patients and 481 treated levels (Table 2). Of these, 4 studies provided data on a mixed group of patients that were treated using both vertebroplasty and kyphoplasty.[14,23,25,28] One kyphoplasty study[38] was a 2-year follow-up that included patients published in a 1-year follow-up study.[39] One vertebroplasty study was published in 2 different journals.[9,10]

All studies on vertebral augmentation procedures were performed primarily on metastatic lesions and/or multiple myeloma (Tables 1, 2), except 1 study.[24] In prospective studies, vertebroplasty[6–11] was used in 98 patients to treat compression fractures due to metastatic disease (74%), multiple myeloma (24%), and hemangiomas (2%). Kyphoplasty[34–40] was used in 204 patients to treat multiple myeloma (55%) and metastases (45%). Some reported procedures performed on patients with hemangiomas,[11,23,27,30,32,33,41] although only 3 patients were clearly noted to have undergone kyphoplasty.[41] Five patients underwent vertebroplasty for lymphoma,[32] 1 patient had chondrosarcoma,[19] and 1 patient had hemangiopericytoma.[33]

Pain Relief

Most studies reported on pain following vertebral augmentation. The various methods of evaluating pain included the Visual Analog Scale, Verbal Rating Scale, McGill and Melzack classification, Site Specific Pain Score, Pain Intensity Numerical Rating Scale, Short-Form 36 Bodily Pain subscore, and self-designed 4-point pain questionnaires to determine whether patients had excellent improvement, good improvement, no improvement, or deterioration. All the studies reported improvement in pain scores. In all, 3 of the studies did not include specific data on pain.[17,23,31] Prospective studies had more detailed pre- and postoperative data and most demonstrated statistically significant results (Table 3). Both techniques were successful at improving pain.

Functional Outcome

Some studies reported on function following vertebral augmentation. The various methods of evaluating function included the Eastern Cooperative Oncology Group Performance Scale, the Townsend Functional Assess-

Table 1. Evidentiary Table for Question 1

		Tumor			Extravasation %				Complications %	
Study	LE	Patients	Levels	Types	Total	Epid	Distal	Sympt	Med	Neuro
Cahana *et al*[6]	II	22	48	M, MM				0	0	0
Cheung *et al*[7]	II	13		M		1		7.7	0	7.7%
Ramos *et al*[8]	II	12	19	MM	84	2	0	0	0	0
Cotten *et al*[9,10]	II	37	40	M, MM	72.5	57.5	0	2	0	8.1
Anselmetti *et al*[11]	II	14	42	M, MM, H	33			0	0	0
Anselmetti *et al*[12]	III	50		M		3.9*		3.9*	0.3*	3.9*
Jang and Lee[13]	III	28	72	M, MM	72.2	26.9	5.8	3.8	7.1	0
Fourney *et al*†[14]	III		65	M, MM	9.2	0	0	0	0	0
Barragan *et al*[15]	III	117	304	M, MM	139				1.7	3.4
Calmels *et al*[16]	III	52	103	M	50.5	26.9	7.7	13.5	5.1	6.8
McDonald *et al*[17]	III	67	114	MM	19	4	0	0	0	0
Alvarez *et al*[18]	III	21	27	M	44	37	0	0	0	4.8
van der Linden *et al*[19]	III	12	12	M, C	58.3		0	0	0	0
Weill *et al*[20]	III	37	52	M	38.5	1	1	9.6	5.4	8.1
Shimony *et al*[21]	III	50	129	M, MM				0	0	0
Hoffmann *et al*[22]	III	14	14	M, MM	57.1	14.3	0	0	0	0
Hentschel *et al*†[23]	III	37†	102*	M, MM, H	19.6*	1*	0	1*	0	1*
Chen *et al*[24]	III	12	12	H				0	0	0
Kose *et al*†[25]	III	16	28	MM				0	3.6	0
Sun *et al*[26]	III	32	51	M	9.8	7.8	0	0	0	0
Muto *et al*[27]	III	30		M, H	37.8*			1.9*	0	1.9*
Masala *et al*†[28]	III	33†	40†	M, MM, H†	35			0	0	0
Caudana *et al*[29]	III	39	62	M, MM	69.4			3.2	0	3.2
Masala *et al*[30]	III	64	198	MM		0	0	0	0	0
Mont'Alverne *et al*[31]	III	12	12	M	58.3		8.3	8.3	0	16.7%
Barbero *et al*[32]	III	37	53	M, MM, H, L	19.6*	5.2*	0	0	0	0
Anselmetti *et al*[33]	III	19		M, MM, HP, H	58*		3.5*	0	0.9*	0

Studies using verterboplasty to treat spine tumors (M indicates metastasis; MM, multiple myeloma or plasmacytoma; H, hemangioma; C, chondrosarcoma; L, lymphoma; HP, hemangiopericytoma).
Question 1: Should cement augmentation be used in patients with painful compression fractures associated with metastatic spine disease?
*Data reported in a mixed group of osteoporosis and tumor.
†Data reported in a mixed group of kyphoplasty and vertebroplasty.
LE indicates level of evidence; Epid, Epidural or foraminal; Sympt, symptomatic; Med, medical; Neuro, neurological.

ment Scale, the Oswestry Disability Index, the Frankel scale, the Roland Morris Disability Questionnaire, the Short Form 36 Physical Function, and self-designed 3- and 4-point gait or mobility scales. Only 5 of the retrospective studies included specific data on function.[17,18,21,24,29] In all 5 studies, functional outcome improved. Prospective studies had more detailed pre- and postoperative data and most demonstrated statistically significant results (Table 3). Both techniques were successful at improving function.

Table 2. Evidentiary Table for Question 1

		Tumor			Complications		Extravasation %				Correction	
Study	LE	Patients	Levels	Types	Med	Neuro	Total	Epid	Distal	Sympt	Height	Kyphosis
Khanna *et al*[34]	II	56		MM	0.5*							
Gerszten *et al*[35]	II	26	26	M	0	0	0	0	0	0	y	y
Dudeney *et al*[36]	II	18	55	MM	0	0	4	2	0	0	y	
Lane *et al*[37]	II	19	46	MM	0	0	26.3	2.6			y^{ss}	
Pflugmacher *et al*[38]	II	65	99	M	0	0	12.1			0	y^{ss}	y^{ss}
Pflugmacher *et al*[39]	II	31	64	M	0	0	12.5		0	0	y	y
Pflugmacher *et al*[40]	II	20	48	MM	0	0	10.4	0	0	0	y^{ss}	y^{ss}
Atalay *et al*[41]	III	10	19	M, MM, H	0	0	2.6*	0		0		
Fourney *et al*†[14]	III		32	M, MM	0	0	0	0	0	0	y^{ss}	y^{ss}
Hentschel *et al*†[23]	III	37†	30*	M, MM, H	0	0	0	0	0	0		
Kose *et al*†[24]	III	18	22	MM	0	0						
Masala *et al*†[30]	III	33†	40†	M, MM, H*	0	0	0	0	0	0	y	y

Studies using kyphoplasty to treat spine tumors (M indicates metastasis; MM, multiple myeloma or plasmacytoma; H, hemangioma).
Question 1: Should cement augmentation be used in patients with painful compression fractures associated with metastatic spine disease?
*Data reported in a mixed group of osteoporosis and tumor.
†Data reported in a mixed group of kyphoplasty and vertebroplasty.
LE indicates level of evidence; y, Yes (y^{ss} statistically significant); Epid, Epidural or foraminal; Sympt, symptomatic; Med, medical; Neuro, neurological.

Table 3. Pain and Functional Outcome Reported in Prospective Studies Using Vertebroplasty and/or Kyphoplasty

Prospective Study	Method	Scale Best-Worst	Patients	Preop (SD)	Postop (SD)	Follow-up	*P*
Pain							
Vertebroplasty							
Cahana *et al*[*6]	VRS	0–5	22	4.8 (0.4)	2.3 (1.1)		<0.001
Cheung *et al*[7]	SPSS	0–10	13			12 w	<0.001
Ramos *et al*[*8]	VAS	0–10	12	7.5 (2.3)	3.3 (2.1)	4 w	<0.001
Anselmetti *et al*[*11]	VAS	0–10	14	8.1 (1.4)	1.0 (1.0)	6 m	<0.001
Cotten *et al*[9,10]	McGill/Melzack	0–5	37†			36 h	
Kyphoplasty							
Khanna *et al*[34]	SF36-BP	100–0	56	28.2 (15.3)	48.0 (20.5)	55 w	<0.001
Gerszten *et al*[35]	VAS	0–10	26	7.5	2.8	4 w	
Dudeney *et al*[36]	SF36-BP	100–0	18	23.2	55.4	7.4 m	<0.001
Lane *et al*[37]							
Pflugmacher *et al*[39]	VAS	0–10	20	8.2	1.9	3 m	<0.05
Pflugmacher *et al*[40]	VAS	0–10	65	8.3 (1.5)	2.9 (0.9)	3 m	<0.001
Function							
Vertebroplasty							
Cahana *et al*[*6]	ECOG-PS	0–4	22	1.9 (1.0)	0.9 (1.0)		<0.001
Cheung *et al*[7]	TFAS	1–4	13			12 w	0.223
Ramos *et al*[*8]	ECOG-PS	0–4	12	3.1 (1.0)	2.4 (1.2)	4 w	0.035
Anselmetti *et al*[*11]	ODI	0–100	14	63.3 (14.1)	10.6 (6.5)	6 m	<0.001
Cotten *et al*[9,10]							
Kyphoplasty							
Khanna *et al*[34]	SF36-PF	100–0	56	26.2 (22.2)	44.2 (26.2)	55 w	<0.001
Gerszten *et al*[35]							
Dudeney *et al*[36]	SF36-PF	100–0	18	21.3	50.6	7.4 m	0.001
Lane JM *et al*[37]	ODI	0–100	19	48.9 (16.6)	32.6 (13.6)	3 m	<0.001
Pflugmacher *et al*[39]	ODI	0–100	20	71.5	22.0	3 m	<0.05
Pflugmacher *et al*[40]	ODI	0–100	65	8.1 (0.8)	3.3 (0.6)	3 m	<0.001

*Data analysis performed using primary data published in the article.
†Partial or complete pain relief obtained in 36/37 patients.
SD indicates standard deviation; VAS, Visual Analog Scale; SPSS, Site-Specific Pain Score; SF-36, short form-36; BP, bodily pain; PF, physical function; VRS, Verbal Rating Scale; ECOG-PS, Eastern Cooperative Oncology Group-Performance Scale; TFAS, Townsend Functional Assessment Scale; ODI, Oswestry Disability Index; RDQ, Roland Morris Disability Questionnaire.
In follow-up, w indicates weeks; m, months; h, hours.

Sagittal Alignment

Most of the studies using kyphoplasty reported some correction in sagittal alignment following surgery,[14,28,35–38,40,41] but only 2 of these[38,40] had reliable long-term data. In 1 study,[40] 20 patients with multiple myeloma were evaluated prospectively and all were available for 1-year follow-up. Initial improvement in vertebral body height was achieved in 64.5% of fractures by a mean of 4.3 mm ($P < 0.05$), while kyphotic deformity was corrected in 78.5% of patients by a mean of 6.3° ($P < 0.05$). At 1 year, the statistical significance was lost as height decreased by 1.1 mm and angulation deteriorated by 1.8°. In the other study,[38] 65 patients with metastatic lesions were treated prospectively and 41 of them were followed for 2 years. The initial height and kyphotic deformities were significantly improved; however, both variables returned to preoperative levels at 2 years.

Studies using vertebroplasty were inconsistent in reporting sagittal alignment. Some authors[8,9,13,18] specified that none of their patients collapsed further, while progressive collapse of the treated level was reported in 3 patients.[17,32]

Complications

Reported complications are generally medical, neurologic, or technical. The prospective studies included 302 patients and reported one possible adverse medical event (Table 4). This was a myocardial infarction that occurred in the postanesthesia care unit, but it is unclear if the patient underwent kyphoplasty for osteoporosis or

Table 4. Summary of Prospective Studies Using Vertebroplasty and Kyphoplasty

Prospective Studies	Verterboplasty	Kyphoplasty
No. studies	5	6
No. tumor patients	98	204
No. tumor levels	152*	330†
Tumor types per patient		
Metastases	73 (74.5%)	91 (44.6%)
Multiple myeloma	23 (23.5%)	113 (55.4%)
Hemangioma	2 (2.0%)	0
Complications		
Medical	0	1/204 (0.5%)‡
Neurological	4 (4.1%)	0
Corrective surgery	3 (3.1%)	0
Extravasation		
Total per level	59/101 (58.4%)	12/239 (12.1%)
Symptomatic patients	3/98 (3.1%)	0
Adjacent vertebral fracture	0	6/204 (2.9%)
Corrective surgery	0	3/204 (1.5%)

*Number may be higher, as Cheung *et al*[7] did not report number of levels per tumor patient.
†Number may be higher, as Khanna *et al*[34] did not report number of levels per tumor patient.
‡Khanna *et al*[34] reported 1 myocardial infarction without specifying if this was a tumor patient.

Table 5. Summary of Studies Using Embolization to Treat Spinal Tumors

Study	Controls	Embolized Patients	Completely Embolized	Unable to Embolize	Permanent Complications	Transient Complications	Tumors	Embolic Agents	Blood Loss
Sundaresan *et al*[42]	13	17	11	2	0	3	Renal (30)	Alcohol (usually) PVA	Embolized 2200 mL
Smith *et al*[43]	0	20	19	0	0	1	Renal (14)	PVA (usually), coils, Gelfoam	871 mL
Vetter *et al*[44]	0	38	27	2	2	1	Thyroid (8), multiple myeloma (7), breast (6)	PVA (26), coils (25), Gelfoam	2400 mL
Jayakumar *et al*[45]	0	12	11	0	0	0	Hemangiomas (12)	Lyophilized dura (6), Gelfoam (5), cyanoacrylate (1)	
Berkefield *et al*[46]	10	59	48	0	0	1	Renal (32), prostate (7), thyroid (6)	PVA only (90), PVA and coils (24), coils only (26)	PVA only 1800 mL PVA and coils 1850 mL Coils only 2650 mL Control 4350 mL
Shi *et al*[47]	0	18	15	0	0	0	Renal (2), other (16)	PVA	
Manke *et al*[48]	10	17	10	1	0	1	Renal (17)	PVA, gelfoam	Embolized 1500 mL Control 5000 mL
Prabhu *et al*[49]	0	51	34	2	2*	0	Renal (30), sarcoma (8)	PVA (9), PVA and coils (38), PVA, coils, and Gelfoam (2)	Embolized 2600 mL
Wirbel *et al*[50]	20	21	19	0	0	0	Renal, thyroid, other	PVA (2), coils (21)	Embolized 1650 mL Control 3880 mL
Guzman *et al*[51]	0	24	22	0	0	0	Renal (14), thyroid (4)	PVA (24), coils (3)	Complete embo 1900 mL Partial embo 5500 mL
Total	53	277	21680.0%	72.5%	41.4%	72.5%	>50% renal	PVA most common	Embolized 2004 mL Control 4278 mL

The level of evidence is III for all studies.
Question 2: Should embolization procedures be used in hypervascular metastatic tumors?
*Asymptomatic cerebellar infarcts.
PVA indicates polyvinyl alcohol particle embolization.

multiple myeloma.[34] None of the retrospective studies on kyphoplasty reported medical complications, while the retrospective vertebroplasty studies identified a total of 11,[13,15,16,25] including 7 pulmonary embolisms,[13,15,16] 1 hemothorax,[16] 2 soft tissue hematomas,[15] 1 wound infection,[25] and 1 death, which resulted from a symptomatic pulmonary embolism.[15] Taken together, the medical complication rate was 1.3% for vertebroplasty and 0.3% for kyphoplasty.

The reported range of radiologic extravasation in vertebroplasty was 9.2% to 139% (multiple areas of extravasations occurred per level), whereas the range was 0% to 26.3% in kyphoplasty. The reported range of symptomatic extravasation in vertebroplasty was 0% to 13.5%, while there were none in kyphoplasty. These complications were better described in the prospective vertebroplasty studies and their sequelae resulted in the 4 neurologic complications (4.1%); 1 patient had a femoral neuropathy due to cement leakage into the psoas muscle that resolved within 3 days,[9] 2 had radiculopathies from nerve root compression following cement leakage and required surgical decompression,[9] and 1 had cement leakage into the spinal canal causing dorsal column dysfunction that required surgical decompression.[6] The retrospective vertebroplasty studies reported a total of 27 patients[15,16,18,20,21,23,29,31] who had symptomatic leaks that led to neurologic deficits (3.4%) that resulted in 4 decompressive[16,20] procedures (0.5%).

Adjacent segment fractures were reported in 6 of the 204 patients[38,40] in the prospective kyphoplasty studies (2.9%). These fractures were symptomatic and required subsequent kyphoplasty correction in 3 cases (1.5%).[38,40] One patient had progressive kyphosis despite successful kyphoplasty and required a decompressive procedure at this level.[35] No other adjacent segment fractures were reported in the retrospective studies. In 1 case,[25] the balloon ruptured during inflation without harming the patient. In the prospective vertebroplasty studies, no adjacent segment compression fractures were reported following vertebroplasty. In the retrospective vertebroplasty studies, 17 patients were reported to have had adjacent level fractures, with 9 who required repeat vertebroplasty.[17,24,29,32,33] The total rate of adjacent segment fracture following verterboplasty was 1.9% and 1.8% following kyphoplasty.

Embolization

The literature search yielded 269 articles of which 201 were in English. No prospective studies were found. Ten retrospective studies[42–51] (level III) were included in the analysis (Table 5). A total of 330 patients were reported, 53 controls who were not embolized and 277 patients who were embolized. Of the embolized patients, 216 of 277 (80.0%) were embolized completely, 54 of 277 (19.5%) were embolized partially, and 7 of 277 (2.5%) could not be embolized. Renal cell carcinoma metastases were the most common lesions treated accounting for more than 50% of lesions treated. Thyroid, breast, and prostate metastases, multiple myeloma, hemangiomas, giant cell tumors, and sarcomas were also among the lesions treated. Polyvinyl alcohol (PVA) was most commonly used for embolization, with coils, alcohol, lyophilized dura, Gelfoam, Dextran, and cyanoacrylate also used.

The overall risk of neurologic complications due to embolization was 4.0%. There were 4 (1.4%) permanent neurologic complications, with 2 being minor as both were asymptomatic cerebellar infarcts seen on magnetic resonance imaging and 2 major brain stem infarcts in embolization of 2 cervical tumors. Transient neurologic complications were seen in 7 (2.5%) and included 2 cases of paraparesis, a conus medullaris syndrome with urinary retention, numbness of the lower extremity, myoclonus, dizziness, and progressive lower extremity weakness, which resolved after surgery. Non-neurologic complications were apparently not reported as there were no groin hematomas, allergic reactions, or contrast induced renal failures. There were no skin or muscle necrosis complications reported.

Blood loss at the time of surgery was significantly reduced with preoperative embolization by over 50%. The average blood loss of those who were embolized was 2004 mL with a range of 1500 to 5500 mL, whereas for controls it was 4278 mL with a range of 3880 to 5000 mL. Sundaresan *et al*[42] noted major complications at the time of surgery related to excessive blood loss in patients not embolized. Berkefeld *et al*[46] compared the blood loss between those embolized and controls and compared embolization with particles, particles and coils, and coils alone, and concluded that particle and particle-coil embolization showed very similar results and reduced hemorrhage significantly as compared to unembolized and coil only occlusion.

■ Discussion

Vertebral augmentation techniques provide a minimally invasive alternative to open surgery in controlling pain due to pathologic compression fractures in selected patients. In some instances, such as multiple myeloma, vertebral augmentation is the treatment of choice due to poor bone quality that frequently precludes successful implantation of screw rod constructs and cages for complex reconstruction. Similarly, transarterial embolization is an important adjuvant to open surgery when dealing with vascular tumors and may be the preferred treatment modality for some tumors, such as aneurysmal bone cysts (ABCs).[52]

Vertebral augmentation is predominantly used to treat painful vertebrae with osteolysis or compression fractures secondary to tumor infiltration. All studies found a statistically significant improvement in pain and function after surgery. Some correction of kyphotic deformity and vertebral collapse was reported following kyphoplasty,[35–38,40] but this may be temporary.[38] The rate of radiologic cement extravasation was 4 times higher using vertebroplasty and resulted in 3 cases of symptomatic cement extravasation following vertebroplasty, which required surgical decompression. Adjacent segment vertebral body fractures occurred more frequently following kyphoplasty with 3 patients requiring secondary kyphoplasty stabilizations. No other medical complications were reported in these studies; however, catastrophic complications have been described in other studies.[15]

There is an ongoing multi-institutional randomized trial of balloon kyphoplasty and nonsurgical care for cancer patients with vertebral compression fractures by the Cancer Patient Fracture Evaluation (CAFE) Study Investigators. Preliminary results were recently presented in a podium presentation (Vrionis, FD. A randomized trial of balloon kyphoplasty and nonsurgical care for cancer patients with vertebral compression fractures. AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, 25th Annual Meeting: Phoenix, AZ, March 11–14). About 21 sites enrolled 70 patients to kyphoplasty and 64 patients to nonsurgical care. The primary endpoint was the 1-month change in the 25-point Roland-Morris Disability questionnaire, while back pain was evaluated using an 11-point scale. Statistically significant improvements were demonstrated in disability and pain following kyphoplasty. There were no significant differences in the number of patients with serious adverse events between 2 groups. While these results have not yet been published in a peer-review journal, they are encouraging and consistent with the results of other prospective studies.

Absolute contraindications to vertebral augmentation include asymptomatic lesions, patients who are improving on medical care, ongoing local or systemic infection, retropulsed bone fragment or epidural tumor causing myelopathy, uncorrectable coagulopathy, and allergy to bone cement or opacification agent.[53] Radiculopathy that is in excess of vertebral pain, caused by tumor or bone fragments, may be better treated by decompressive surgery and/or radiation therapy. In general, radiation therapy, radiosurgery, and chemotherapy are used to treat the underlying neoplastic component. Some have recently combined vertebral augmentation with radiofrequency ablation[19,22,28] or direct alcohol injection[23] to improve local control.

Embolization of spinal tumors has been advocated since the 1960s. Tumors most commonly reported and that seem to benefit most from embolization are highly vascular tumors such as metastic renal cell and thyroid carcinoma, hemangiomas, and ABCs. Preoperative embolization has been shown to decrease blood loss at the time of surgery, which is believed to decrease surgical morbidity, shorten the operative procedure time, increase the chances of complete surgical resection, decrease the risk of damage to adjacent normal tissue, and finally allow better visualization of the surgical field with decreased overall surgical complications.

The most significant and feared risk of paraplegia/quadriplegia due to spinal cord ischemia/infarction from embolization of spinal cord vessels and in particular the artery of Adamkiewicz was not reported in the studies reviewed. Nonetheless, the risks related to spinal angiog-

raphy are sufficient to dissuade its common practice in preoperative planning for cases where embolization is not sought. The only exception, in our experience, is if segmental feeders are to be disrupted bilaterally at any 1 level between T8 and L2.

Embolization has been reported with PVA, coils, Gelfoam, glue (N-butyl cyanoacrylate), Onyx (ethylene vinyl alcohol polymer), Embospheres, and alcohol. PVA is most commonly used providing an inexpensive material that penetrates the tumor bed very effectively. Larger particles reduce chance of cord and skin infarction. Embolized vessels will recanalize over several weeks and so surgery is ideally performed within a few days of embolization. Given that embolization is generally performed before surgery, there is no need to use permanent embolic agents such as glue, Onyx, embospheres, and alcohol.

Direct percutaneous embolization is also possible as an adjunct to or instead of transarterial embolization.[54] Recently, transarterial embolization for palliation alone has been reported to offer rapid and lasting relief of pain, improve neurologic symptoms, and provide local control of tumor growth.[55] This is particularly true of giant cell tumors. Boriani *et al*[52] treated 4 ABCs with embolization alone for curative purposes with 3 having no recurrence and suggested arterial embolization may be the treatment of choice in managing these tumors. Another technology is chemoembolization that combines intra-arterial local chemotherapy and embolization. This technique has been shown to provide durable pain relief with up to 30% demonstrating a radiologic response.[56]

■ Conclusion

The percutaneous techniques reviewed for the treatment of spinal tumors offer numerous advantages and greatly enhance our ability to treat complex, refractory, and palliative cases. Numerous prospective studies support vertebroplasty and kyphoplasty as both safe and effective treatment methods in spinal metastases.

Question 1: Should cement augmentation be used in patients with painful compression fractures associated with metastatic spine disease? The SOSG recommends cement augmentation in patients with painful compression fractures secondary to metastatic spine disease. Strong Recommendation, moderate quality evidence. Each cement augmentation modality has its advantages and the better technique will ultimately depend on the comfort-level of the treating clinician.

Embolization is less well studied but overwhelming clinical experience suggests it is safe and effective in decreasing intraoperative blood loss in hypervascular tumors.

Question 2: Should embolization procedures be used in hypervascular metastatic tumors? We recommend embolization procedures to reduce operative blood loss in hypervascular tumors. Strong Recommendation, very low quality evidence. Future research in this field will depend on collaborative efforts among cancer centers to further our knowledge on the usefulness, safety, and applicability of these percutaneous procedures.

■ Key Points

- There is strong recommendation and moderate evidence for the use of vertebral augmentation procedures in alleviating pain and improving function in patients with osteolysis or compression fractures secondary to tumor infiltration.
- Vertebral augmentation is most commonly used to treat pain in metastatic and multiple myeloma lesions.
- There is strong recommendation and very low evidence for transarterial and percutaneous direct embolization in reducing intraoperative blood loss.
- Further research is required to confirm these results.

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